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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,433	07/27/2001	Laurence Lee	P430.12-0002	2032

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EXAMINER
BLANTON, REBECCA A

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,433	Applicant(s) LEE ET AL.
	Examiner Rebecca A. Blanton	Art Unit 1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18 and 26-30* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12 October 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-16, 18, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glatt et al. (U.S. 4,858,552) in view of Reynolds (U.S. 3,354,863).

Referring to claims 13, 26, and 30, Glatt et al. disclose a fluidized bed apparatus capable of spraying, coating, and drying pellets of pharmaceutical material (column 1 lines 27-38 and column 2 lines 15-21). The fluidized bed, disclosed by Glatt et al., comprises a perforated base through which fluidizing gas flows, a channeling chamber such as a cylindrical rising tube, and a spray nozzle (column 2 lines 54-68 and column 3 lines 1-8). In column 3 lines 63-65, the reference teaches that the channeling cylinder may be vertically adjusted to adapt to different process conditions. The reference further teaches that the spray nozzle may also be adjusted vertically to allow for

different particle sizes and densities (column 3 lines 52-56, and 66-68 and column 4 lines 1-2). Glatt et al. disclose that the particles are carried upwards through the bed and are deflected outward and carried to the lower inlet area of the rising tube to allow for the particles to increase in size during the process (column 3 lines 31-36, and 50-53). Glatt et al. teach that the particles are loaded into the bed, and then are fluidized by an upward flowing gas (column 3 lines 22-36). In Figure 1, Glatt et al. show that the spray nozzle is adjusted to form a coating region inside of the cylindrical chamber. Furthermore, Glatt et al. teach that the circulating fluid allows for drying of the particles during the coating and agglomeration process (column 3 lines 15-21). The particles are circulated through the fluidized bed several times until the particles have reached the appropriate size (column 3 lines 50-55). Glatt et al. disclose that a multi-medium nozzle, which comprises liquid and gaseous components where the gaseous components atomize the liquid, is used as the spraying means for the coating liquid (column 6 lines 24-35). The reference further teaches that the spraying liquid may be heated to prevent the liquid from solidifying (column 6 lines 33-35). Glatt et al. do not teach positioning the spray nozzle in a non-heat conduction relation to the bottom screen. Reynolds teaches a method of coating particles with a liquid and drying the coating (column 1 lines 10-13). The coating apparatus, taught by Reynolds, comprises a cylindrical chamber in the fluidized bed, through which the coating fluid is sprayed, a spray nozzle, which has a coating fluid and an atomizing fluid, and a perforated base through which the fluidizing gas flows (Figure 1 and column 1 lines 27-54). Reynolds discloses that the particles circulate through the apparatus by flowing upward through

the cylindrical coating section and flowing downward in the drying section, outside of the cylindrical chamber (column 1 lines 55-42 and column 2 lines 1-5). Reynolds discloses that the spray nozzle comprises a coating material and an atomizing fluid and may be positioned above the perforated plate in a non-heat conducting manner, or it may be positioned flush with the perforated plate (Figure 1 and column 5 lines 24-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to position the spray nozzle in the fluidized bed coating/agglomeration apparatus, taught by Glatt et al., above the perforated plate in view of the teaching of Reynolds that placing the nozzle flush with the plate is equivalent to placing it above the perforated plate in a non-heat conducting relation to the perforated plate.

Referring to claims 14 and 15, Glatt et al. disclose that the fluidized spray is used to agglomerate and coat the particles in the fluidized bed (abstract).

Referring to claims 16 and 27, Glatt et al. discloses that the spraying liquid may be a liquid fat (column 7 lines 11-14).

Referring to claims 18 and 28, in column 3 lines 50-68, Glatt et al. teach that the liquid sprayer is height adjustable. In Figures 1 and 10, Glatt et al. show that the spray nozzle is adjustable below the bottom edge of the cylindrical chamber.

Referring to claim 29, Glatt et al. do not disclose a method for removing the coated particles from the fluidized bed. However, Reynolds teaches the use of a product line that removes coated particles from the bottom of the bed during the fluidization process, so that the cylindrical chamber is not removed from the fluidized bed during product removal (Figures 1 and 2 and column 1 lines 40-42, and 51-53). It

would have been obvious to one of ordinary skill in the art at the time the invention was made to look to prior art for a method of removing the coated particles from the fluidized bed taught by Glatt et al., in the absence of a teaching for removing the product particles, and to use the product line, in view of the teaching of Reynolds to remove the product particles without disturbing the cylindrical partition within the chamber.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glatt et al. (U.S. 4,858,552) in view of Reynolds (U.S. 3,354,863) as applied to claim 13 above, and further in view of Biehl et al. (U.S. 4,217,851).

Glatt et al. and Reynolds disclose methods for coating particles using a fluidized bed, as described above. However, neither reference discloses the diameter-to-height ratio of the cylindrical portion in the fluidized bed. Biehl et al. disclose a fluidized bed coating apparatus that comprises a perforated plate, through which the fluidizing gas flows, a spray nozzle, and a cylindrical coating chamber (Figure 1 and column 2 lines 47-68). In column 4 lines 50-58, Biehl et al. teach that the particles flow upward through the cylindrical coating chamber, where they are sprayed with coating liquid. In Figure 1, the diameter of the cylindrical chamber appears to be equivalent to the length of the chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made, in absence of a specific diameter-to-length ratio being disclosed by Glatt et al. or Reynolds, to use a ratio equal to one as disclosed by Biehl et al.

Allowable Subject Matter

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The applicant's limitation, in claim 19, that the inlet air temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure are all monitored distinguishes over Glatt et al. because the reference does not teach monitoring all of these parameters at the same time.

None of the prior art of record teaches or makes obvious the applicant's claimed invention of a fluidized bed coating and agglomerating apparatus that measures all of the above mentioned parameters for the same coating process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca A. Blanton whose telephone number is 703-605-4295. The examiner can normally be reached on M - F (7:30am - 3:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

rab RAB
January 23, 2002

SHRIVE P. BECK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700